EFAFLEX
safe high-speed doors

Serie CR

The Clean Room

Serie CR

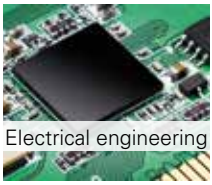
What is a clean room?

A clean room (CR) is a room in which the air must be kept free of particles, this is done by minimizing airborne matter. Generally, it is a segregated area whose degree of cleanliness is determined by the cleaned air introduced using overpressure.

What you should know about clean rooms

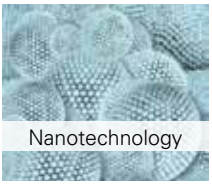
Where are clean rooms used?

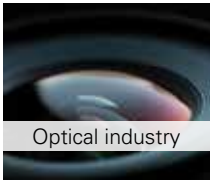
Clean rooms are predominantly used in the semiconductor, pharmaceutical, medicine and biotechnology, aerospace industries and by life science producers (food, beverage, tobacco and related areas).


Electrical engineering


Biotechnology


Aerospace


Nanotechnology


Optical industry


Pharmaceuticals


Medical Engineering


Solar/photovoltaics


Cosmetics

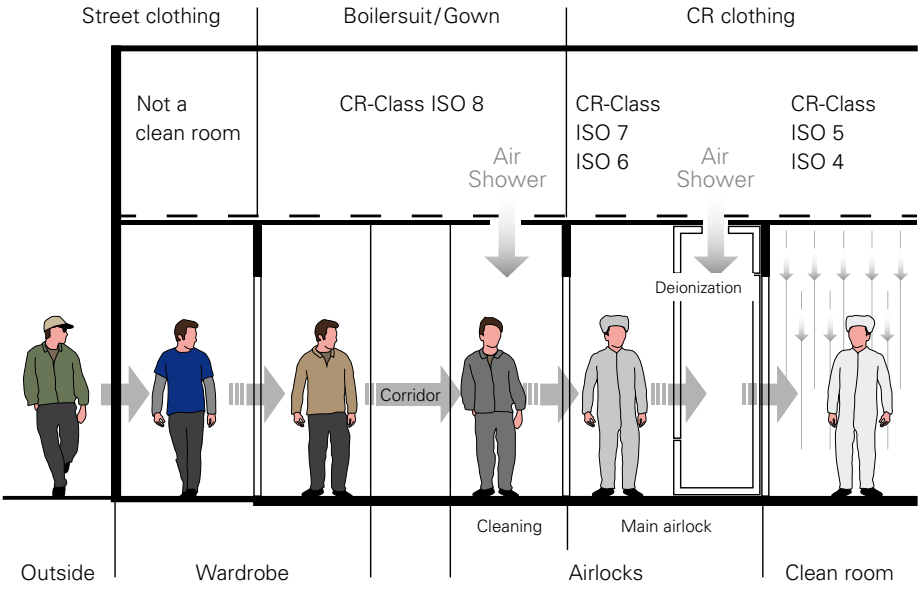

Packaging industry


Plastic moulded components


Chemistry & environmental analytics

What characterizes a clean room?

- Environmental conditions are maintained at a constant (temperature, light, pressure, air humidity)
- Personnel wear protective clothing
- People and materials can only gain access through airlocks



What are clean room classes?

According to EN ISO 14644-1 clean rooms are divided into classes, determining their degree of cleanliness (particle count and size). Classification ranges from ISO 1 (highest standard) to ISO 9 (signifies clean air).

The EFA-SRT® CR Premium has been certified by TÜV for use in clean rooms.


ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT

Zertifikat

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Dipl. Ing. Reiner Hoffstadt

EFA-SRT® CR Premium

CLEAN ROOM CLOTHING	CLEAN ROOM CLASS			
ISO 14644	8	7	6	5
Overalls	–	•	•	•
Protective hood Full protection	–	•	•	•
Boots	–	–	•	•
Coat	•	–	–	–
T-Shirts		•	•	•
Trousers	•	•	•	•
Overshoes	•	•	–	–
Face mask	–	–	•	•
Gloves	•	•	•	•
Disposable hood	•	•	•	•
Change frequency	1/week	1-2/week	2/week	per entry

What is permissible particle concentration?

Permissible particle concentration is the maximum number of particles which are permitted to be present in the air in the clean room. Particle of sizes ≥ 0.5 µm to 5 µm are measured, with the air conditioning system running, both during standstill and during production. Air conditioners with multi-stage filters are used to achieve particle/germ free air.

The EFA-SRT® CR Premium can be used for up to clean room class 5.

In comparison

Particle emission of one person without clean room clothing per minute while seated (e.g. in front of PC): approx. 500,000 particles.

Clean room class according to ISO 14644-1	STANDSTILL		OPERATION	
	Maximum permissible particle count/m³, greater than or equal to			
	0,5 µm	5,0 µm	0,5 µm	5,0 µm
ISO 5 = A	3.520	20	3.520	20
ISO 6 = B	3.520	29	352.000	2.900
ISO 7 = C	352.000	2.900	3.520.000	29.000
ISO 8 = D	3.520.000	29.000	not defined	not defined

What does GMP mean?

GMP is the abbreviation of "Good Manufacturing Practice". It refers to guidelines for quality assurance in production of drugs, active ingredients and medical devices. It applies to personnel, environment, equipment and documentation. Production and sales are subject to regulatory approval and are monitored by supervisory authorities. Any deficiencies can result in loss of the production licence.

What is a GMP zone concept?

The most important aim of GMP measures is to protect the products against contamination with foreign particles (other actives, germs etc.).

The EFA-SRT® CR Premium has been developed in cooperation with TÜV to satisfy GMP requirements.

For many products, the production processes must take place in hygiene zones of different cleanliness classes. In general, the more critical the process, the lower the ISO class number required. For ISO classes, specific requirements apply on particle and germ concentration, clean air treatment and air exchange, surfaces of rooms and equipment, work clothing, monitoring and documentation.

Materials and personnel may only transition between GMP classes through separate airlocks. The airlocks require door locking systems operable from both sides (e.g. traffic light control). Materials are purified and personnel disinfected in the separate airlocks.

The EFA-SRT® CR Premium has been certified by TÜV and can be used for up to ISO Class 5 in agreement with the operators.

ISO 14644	EU/USA	RESPECTIVE CLASSES
ISO 5	A/100	Aseptic (sterile) production and filling
ISO 6	B/1.000	Ambient conditions around ISO Class 5
ISO 7	C/10.000	Preparation of solutions and ointments
ISO 8	D/100.000	Production and filling of tablets/capsules (Oralia)

GMP CLASS	APPLICATION
A	Zones for high risk operations
B	For aseptic preparation and filling; the background environment for a grade A zone
C	Zones for carrying out more critical phases in the production of sterile products
D	Zones for carrying out less critical phases in the production of sterile products

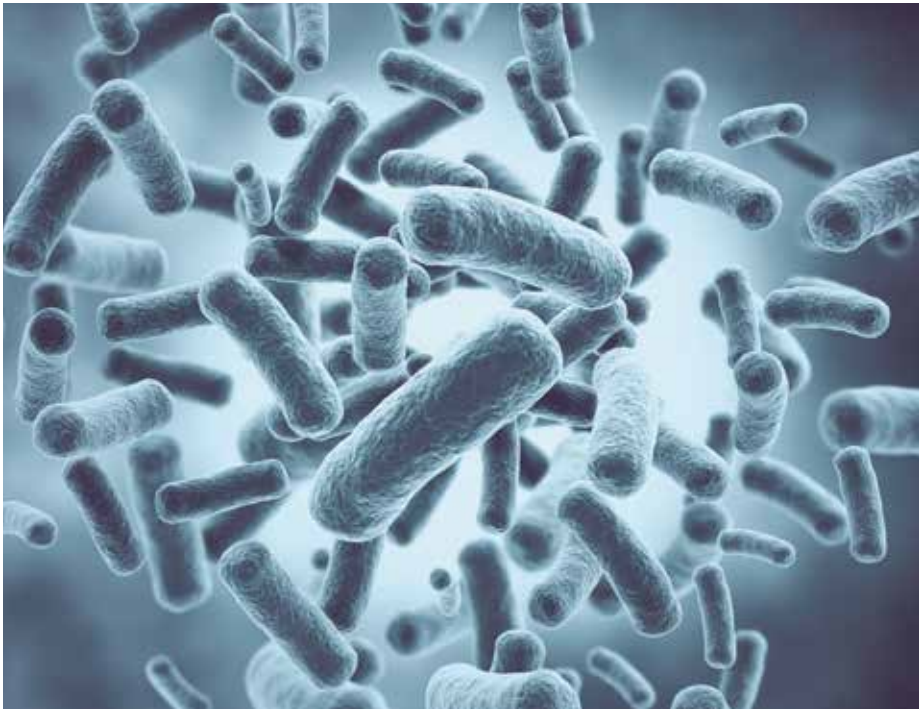
What GMP requirements exist for components?

Components must not give off particles and must be easy to clean and easy to disinfect. Typical conditions would be:

- Smooth surfaces without cracks or sharp edges
- Resistance to cleaning agents and disinfectants
- Surface material is typically stainless steel with a maximum surface roughness of ≤ 0.8 µm

The EFA-SRT® CR Premium has been designed in compliance with GMP guidelines and fulfils the requirements for the cleaning of surfaces and recesses.

The requirements prescribed for product-carrying materials do not apply to our door, since it does not normally come into contact with the product.



How do you qualify according to GMP?

In the scope of certification, EFAFLEX has created all necessary supporting documentation (checklists, operating instructions). All further documents must be created by the operator.

GMP compliant clean rooms and systems must be qualified and clean room processes validated. Qualification is the documented evidence that the room and system are suitable for the intended purpose.

These include:

- Performance/system specification
- Risk analysis
- Qualification and validation of master plans
- Design qualification
- Installation qualification
- Functional qualification
- Performance qualification
- Calibration
- Maintenance
- Process validation
- Cleaning validation

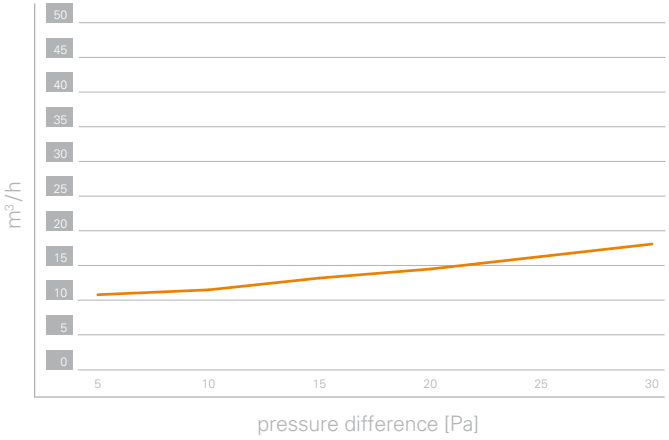
What is a pressure stage concept?

The excellent airtightness of the EFA-SRT® CR Premium has been measured and confirmed by several neutral assessment authorities.

The pressure stage concept guarantees no air currents from the unclean area can enter the clean area when the doors are opened. The pressure difference between rooms of different ISO/GMP classes must resist to 15 Pa. These pressures can only be achieved if the building structures (walls, ceilings, windows, doors) are airtight. In the area where ISO/GMP classes change pressure its maintained at a constant level, while exhausted air is adapted by volume flow controllers.

Measured air leakage (m^3/h)

(measured with greater pressure on mounting side)
Air leakage depends on door size, linear interpolation does not apply.



EFA-SRT® CR Premium
Door size 2.500 x 2.500 mm

What does air exchange rate mean?

Air exchange rate refers to how frequently the total amount of air in a clean room is renewed per hour. In clean rooms, certain air exchange rates are prescribed in order to minimize airborne particle and germ counts.

The air exchange rates can be achieved with the EFA-SRT® CR Premium, where adherence remains the operator's responsibility.

CLEAN ROOM CLASS	ISO 6/100/GMP B	ISO 7/10.000/GMP C	ISO 8/100.000/GMP D
Air exchange/hour	30 – 70-times	20 – 60-times	15 – 25-times (recommended)

What is clean room monitoring?

Clean room monitoring involves continuous measurement of air exchanges, particle concentrations, germ counts and room pressure differences. The methods and instruments used are defined in ISO EN 14644-3.

In the scope of certification of the EFA-SRT® CR Premium, all necessary requirements were satisfied; clean room monitoring remains the operator's responsibility.

What are SOPs?

SOP stands for "Standard Operating Procedure". In a GMP operation, all measures such as manufacturing processes, quality control methods, operating instructions, cleaning instructions etc. are described and controlled in the form of SOPs.

The standard documentation available for the EFA-SRT® CR Premium clean room door satisfies the corresponding SOPs.

Notes

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Technological advancement. Pioneering design.

For more than 40 years, EFAFLEX has developed and designed reliable and highly-efficient high-speed doors. With innovative technology and pioneering solutions for special requests, EFAFLEX continually provides the market with new stimuli. This leadership role through superior technology, the best quality and a maximum degree of security is part of EFAFLEX's identity. More than 1,000 employees guarantee competent consultation and excellent service. Worldwide and always near you.

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